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10/517,277	04/05/2006	Radka Milanova	7865-206 MIS:jb	2819

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EXAMINER

TSAY, MARSHA M

ART UNIT	PAPER NUMBER
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1656

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03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,277	Applicant(s) MILANOVA ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 and 48-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46, 48-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

This Office action is in response to Applicants' remarks received December 17, 2007.

Claim 47 is canceled. Claims 1-46, 48-53 are currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Priority: The priority date is June 21, 2002.

Objections and Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-46, 48-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for removing solvent from the extracted oil seed meal at a temperature of from 20°C to 50°C to provide a desolventized oil seed meal, does not reasonably provide enablement for removing solvent from the extracted oil seed meal at any temperature below 50°C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to ascertain how solvent can be removed from the extracted oil

Art Unit: 1656

seed meal any temperature below 50° C and/or which temperatures below 50°C can provide a desolventized oil seed meal. Thus for the instant claimed invention, it would require an undue burden of experimentation for a skilled artisan to determine exactly which temperature will yield the highest concentration of a dried rapeseed oil seed meal.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case the quantity of experimentation would be large since any temperature below 50°C can be chosen, i.e. 15°, -10°C, -30°C, etc. The amount of guidance is minimal with regard to how temperatures below 50°C can be used to provide a desolventized oil seed meal. It is known in the art that 0°C is the freezing point of water. In Examples 1-3 (specification p. 15-

Art Unit: 1656

20), Applicants appear to disclose an air-desolventized temperature of 20°C. Therefore, according to the instant specification, it appears as if the rapeseed is enabled for an air-desolventized temperature of 20°C. The nature of the invention is such that a change in temperature may decrease the protein content of the rapeseed protein isolate and/or affect its structural properties. The state of the prior art is that rapeseed proteins are sensitive to their environment and any changes to its physical environment may decrease the protein content of the rapeseed protein isolate and/or affect its structural properties. The relative level of skill in this art is very high. The predictability as to which temperatures below 50°C will yield a rapeseed protein content of at least about 90 wt % is zero.

When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claim is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-46, 48-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-46, 48-53 contain the trademark/trade name “canola”. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product.

Art Unit: 1656

A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe rapeseed and, accordingly, the identification/description is indefinite. This rejection can be overcome by amending “canola” to “rapeseed.”

Claims 5-10, 11-12, 13-24 recite said extracting of said oil seed meal is effected using an aqueous salt solution. It should first be noted that Examples 1-3 of the instant specification (p. 15-20) disclose that it is samples of air-desolventized canola oil seed meal are subject to agitation with aqueous salt solution, and not the initial oil seed meal obtained from crushing the oil seeds. Therefore, it would appear that it is the desolventized oil seed meal that is effected using an aqueous salt solution. However, the instant claims recite that it is the oil seed meal that is effected using the aqueous salt solution; therefore, the claims are indefinite because it is unclear which oil seed meal, i.e. the oil seed meal of claim 1b or the desolventized oil seed meal of claim 1d, is effected with the aqueous salt solution, in view of the specification. Further clarification and/or correction is requested.

Claims 29, 31-32, 34 recite said protein solution is diluted by about 15 fold or less to achieve the desired degree of dilution. The instant claims are indefinite because the claims recite a desire to obtain a degree of dilution; however, the claims recite the dilution is 15 fold or less, which can encompass a zero fold dilution and therefore, no degree of dilution.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1656

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-10, 17-19, 29-31, 35, 44-48 remain rejected under 35 U.S.C. 103(a) as being obvious over Murray (US 6005076; IDS).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

In Example 3 (col. 7, lines 60-67), Murray discloses a process of initially preparing a protein isolate using a meal prepared from the cold pressing of canola seeds to give a consistency similar to canola meal, followed by a protein extraction and recovery process (as described in Example 2). In Example 2, Murray discloses that meal from rapeseed containing 32.5% protein, 10.1% fat and 6.1% moisture was extracted with an aqueous salt solution and agitation (col. 7

Art Unit: 1656

lines 37-40). It would be reasonable for one of ordinary skill to recognize that the initial rapeseed meal having a moisture content of 6.1% would be essentially a dried meal product that is desolventized. The aqueous meal/salt solution was mixed for 2 hours at 25°C to remove residual meal and then chilled to 8°C followed by centrifugation (col. 7 lines 5, 40-43). Murray discloses the aqueous salt solution with an ionic strength value of less than 0.8 and within the range of 0.3 to 0.6 (col. 8, lines 62-63), a pH range of 5.3 to 6.2 (col. 8, line 66-67), and wherein the aqueous protein solution has a concentration of about 10-100 g/L of protein (col. 9, lines 1-3). In addition, Murray discloses that the formation of protein isolates into micelles is achieved optimally at pH values of 5.3 to 6.2 (col. 3, lines 46-50). After separating the aqueous protein solution from the residual oil seed meal, Murray discloses a process step for increasing the protein concentration using a selective membrane technique, diluting the concentrated protein solution by 15 fold at 6° C to form protein micelles, settling the protein micelles, and recovering the protein mass to provide a dried proteinaceous powder having a protein content of at least 90 wt % (col. 7, lines 12-30, col. 8, lines 31-61). Murray does not explicitly teach a desolventized oil seed meal.

It would have been obvious to a person having ordinary skill in the art to crush canola seeds (claim 1), extract the oil seed meal by a suitable solvent (claim 1, 2), such as hexane or an aqueous salt solution (claim 1, 2, 5), subject the extraction system to a temperature of 25°C (claim 1c) and then chilled at 8°C to remove fat content to obtain a crude protein extract followed by centrifugation to obtain a desolventized meal (claim 1, 2, 5), maintain the aqueous solution at an ionic strength and pH range that is suitable for the formation of protein micelles (claim 1, 2, 5-10, 17-19), increase the protein concentration (claim 1), dilute the concentrated

Art Unit: 1656

protein solution to induce the formation of protein micelles (claim 1, 2, 29-31), settle the protein micelles, and recover the protein micelles to make a dry proteinaceous powder having a protein content of at least 90 wt % (claim 1, 35) because Murray provides and suggests motivation for preparing a protein isolate from canola oil seed meal that involves a step of lowering the extraction system to a temperature below 50°C, i.e. 25°C.

Though, Murray provides working examples using canola meal, the process may be used for other oil seed meals, such as soybean meal and rapeseed meal (col. 2, lines 60-62), as well as proteinaceous material, such as proteins from naturally occurring oil seeds or proteins obtained by genetic manipulation (col. 2, lines 62-65). In col. 3, Murray also discloses that the canola meal may be any canola meal resulting from canola seed with varying levels of non-denatured protein, from hot hexane extraction or cold oil extrusion methods (col. 3, lines 1-5).

It would have been obvious to a person having ordinary skill in the art to prepare a protein isolate with any appropriate oil seed meal (claim 1, 44-48) because Murray provides and suggests motivation for using a proteinaceous material to prepare a protein isolate having a protein content of at least 90 wt % (col. 8 lines 31-61).

In their remarks, Applicants concede that the Murray reference describes steps (d) to (i) of instant claim 1. However, Applicants submit that the Murray reference does not disclose or suggest the combination of steps (a) to (c) of claim 1 with steps (d) to (i). Applicant's arguments have been fully considered but they are not persuasive.

The 35 U.S.C. 103(a) rejections are maintained in view of the indefiniteness issues noted above regarding claims 5-10, 11-12, 13-24, i.e. whether it is the oil seed meal or the

Art Unit: 1656

desolventized oil seed meal that is effected by the salt solution. Further, as noted above, Murray discloses that rapeseed meal containing a moisture content of 6.1% is extracted with an aqueous salt solution and agitation (col. 7 lines 37-40). It would be reasonable for one of ordinary skill to recognize that rapeseed meal having a moisture content of 6.1% is a dried oil seed meal product which is functionally equivalent to a desolventized oil seed meal. Therefore, Murray suggests a desolventized oil seed meal even if not explicitly stated.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

Art Unit: 1656

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

March 7, 2008